



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1012; FRL-9941-38]

Pyriproxyfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases the currently established tolerance for residues of pyriproxyfen in or on tea from 0.02 parts per million (ppm) to 15 ppm. Sumitomo Chemical Company, Ltd., c/o Valent U.S.A. Corporation, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-1012, is available at <http://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-1012 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-1012, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 2, 2015 (80 FR 75449) (FRL-9939-55), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP #4E8326) by Sumitomo Chemical Company, Ltd., c/o Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.510 be amended to increase the currently established tolerance for residues of pyriproxyfen in/on tea from 0.02 ppm to 15.0 parts per million (ppm). That document referenced a summary of the petition

prepared by Sumitomo Chemical Company, Ltd., c/o Valent U.S.A. Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no substantive comments received in response to the notice of filing.

Based upon review of the data supporting the petition, the petitioned-for tolerance for residues of pyriproxyfen in/on tea (15.0 ppm) must be corrected to 15 ppm, consistent with current practices for setting tolerances. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the

hazards of and to make a determination on aggregate exposure for pyriproxyfen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriproxyfen follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Pyriproxyfen elicits low acute toxicity by oral, dermal, inhalation, and ocular routes of exposure. Pyriproxyfen is not a skin irritant and was negative in the dermal sensitization study in guinea pigs. Based on repeated dose studies in mice, rats, and dogs the liver, kidney, and hematopoietic system are the primary targets of pyriproxyfen. Neurotoxicity, in the form of reduced motor activity, occurred only at a doses well above those required to elicit toxicity in the liver, kidney, and hematopoietic system indicating the nervous system is not a principle target. There was no evidence of prenatal or postnatal sensitivity or increased susceptibility in developmental toxicity studies in rats and rabbits, and in a 2-generation reproduction toxicity study in rats. An immunotoxicity study showed no adverse effects on the immune system. No significant systemic toxicity was observed in the 21-day dermal toxicity study in rats. In a 28-day inhalation study, salivation in females and sporadic decreased body weight gains in males was observed at 1 milligram/Liter (mg/L); however, these effects were not considered biologically

relevant. There is no evidence for carcinogenicity to humans based on the absence of carcinogenicity in mice and rats. Pyriproxyfen is negative for mutagenic activity in a battery of mutagenicity studies conducted with both the parent and/or metabolites. Specific information on the studies received and the nature of the adverse effects caused by pyriproxyfen as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> on pp. 10-18 in the document titled “Pyriproxyfen. Human Health Risk Assessment for the Petition to Increase the Established Tolerance in/on Tea with a U.S. Registration for Imported Pyriproxyfen-treated Tea.” in docket ID number EPA-HQ-OPP-2011-1012.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the

general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Pyriproxyfen for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	An appropriate endpoint attributable to a single oral dose was not identified in the toxicology database, including the developmental and reproduction toxicity studies.		
Chronic dietary (All populations) ¹	NOAEL = 35.1 mg/kg/day UF _A = 10x UF _H =10x FQPA SF= 1x	Chronic RfD = 0.35 mg/kg/day cPAD = 0.35 mg/kg/day	Subchronic (41321716) and chronic (43210503) – rat (co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and body weight gain, anemia, and increased relative liver weight with elevated cholesterol and phospholipid levels.

Incidental oral short-term (1-30 days)	NOAEL = 100 mg/kg/day UF _A = 10x UF _H =10x	LOC for MOE = 100	Rat developmental toxicity (44985002) Maternal LOAEL = 300 mg/kg/day based on decreased body weight, body weight gain, and food consumption, and increased water consumption.
Incidental oral intermediate-term (1-6 months) ¹	NOAEL = 35.1 mg/kg/day UF _A = 10x UF _H =10x	LOC for MOE = 100	Subchronic (41321716) and chronic (43210503) – rat (co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and body weight gain, anemia, and increased relative liver weight with elevated cholesterol and phospholipid levels.
Dermal short- and intermediate-term (1-30 days and 1-6 months)	Based on the systemic toxicity NOAEL of 1,000 mg/kg/day (limit dose) in the 21 day dermal toxicity study in rats, quantification of dermal risks is not required. In addition, no developmental concerns (toxicity) were seen in either rats or rabbits.		

Dermal long-term (6 months-lifetime) ¹	NOAEL = 35.1 mg/kg/day DAF = 30% ² UF _A = 10x UF _H =10x	LOC for MOE = 100	Subchronic (41321716) and chronic (43210503) – rat (co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and body weight gain, anemia, and increased relative liver weight with elevated cholesterol and phospholipid levels.
Inhalation short- and intermediate-term (1-30 days and 1-6 months)	Based on the absence of biologically relevant toxicity at 1.0 mg/L, the quantification of inhalation risks is not required. In addition, no developmental concerns (toxicity) were seen in either rats or rabbits.		
Inhalation long-term (6 months-lifetime) ¹	NOAEL = 35.1 mg/kg/day UF _A = 10x UF _H =10x	LOC for MOE = 100	Subchronic (41321716) and chronic (43210503) – rat (co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and body weight gain, anemia, and increased relative liver weight with elevated cholesterol and phospholipid levels.
Cancer (Oral, dermal, inhalation)	No evidence of carcinogenicity in mice and rats (TXR 0012966).		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures.

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies).

UF_H = potential variation in sensitivity among members of the human population (intraspecies). DAF = dermal absorption factor.

¹The NOAEL and LOAEL for the co-critical studies were based on the female endpoints from the chronic and sub-chronic rat studies, respectively. Females demonstrated greater or equivalent sensitivity to oral pyriproxyfen exposure relative to males; therefore, selection of two female endpoints accounted for effects observed in the males and preserved consistency between the NOAEL and LOAEL.

²DAF estimated by comparing the rat developmental LOAEL of 300 mg/kg/day to the 21-day rat dermal study NOAEL of 1,000 mg/kg/day (No NOAEL) = $300/1,000=30\%$.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyriproxyfen, EPA considered exposure under the petitioned-for tolerances as well as all existing pyriproxyfen tolerances in 40 CFR 180.510. EPA assessed dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for pyriproxyfen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that pyriproxyfen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyriproxyfen. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pyriproxyfen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyriproxyfen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model and the Generic Estimated Exposure Concentration (GENEEC) model the estimated drinking water concentrations (EDWCs) of pyriproxyfen for chronic exposure assessments are estimated to be 2.98 parts per billion (ppb) for surface water and 0.006 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.98 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to nonoccupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyriproxyfen is currently registered for flea and tick control (home environment and pet treatments) as well as products for ant and roach control (indoor and outdoor applications). Formulations include carpet powders, foggers, aerosol sprays, liquids (shampoos, sprays, and pipettes for pet treatments), granules, bait (indoor and outdoor), and impregnated materials (pet collars). EPA assessed residential exposure using the following assumptions: Although there is the potential for short-term residential handler dermal and inhalation exposure as well as short or intermediate-term post-application exposure from the registered uses of pyriproxyfen, there are no short or intermediate-term dermal or inhalation PODs and quantitative assessments were not conducted.

Based on the registered use patterns, the following post-application scenarios were assessed: Short- and intermediate-term hand-to-mouth exposures for 1 to <2 year olds from treated carpets and flooring and petting treated animals (shampoos, sprays, spot-on treatments and collars); long-term hand-to-mouth exposures for 1 to <2 year olds from treated carpets and flooring and petting treated animals; and long-term dermal exposures from treated carpets, flooring, and pets.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found pyriproxyfen to share a common mechanism of toxicity with any other substances, and pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action; therefore, EPA has assumed that pyriproxyfen does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Based on the available data, there is no quantitative and qualitative evidence of increased susceptibility observed following *in utero* pyriproxyfen exposure to rats and rabbits or following prenatal/postnatal exposure in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for pyriproxyfen is complete.
- ii. There is no indication that pyriproxyfen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that pyriproxyfen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyriproxyfen in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyriproxyfen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pyriproxyfen is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyriproxyfen from food and water will utilize 12% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. A long-term post-application residential assessment was performed for toddlers only since they are anticipated to have higher exposures than adults from treated home environments and pets due to their behavior patterns. The total chronic dietary and residential aggregate MOE is 230 for children 1 to <2 years old. As this MOE is greater than 100, the chronic aggregate risk does not exceed EPA's level of concern.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyriproxyfen is currently registered for uses that could result

in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pyriproxyfen.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 2,200 for children 1 to <2 years old, the population subgroup receiving the greatest exposure. Because EPA's level of concern (LOC) for pyriproxyfen is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Pyriproxyfen is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to pyriproxyfen.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 760 for children 1 to <2 years old, the population subgroup receiving the greatest exposure. Because EPA's LOC for pyriproxyfen is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyriproxyfen is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyriproxyfen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography with Nitrogen-Phosphorous Detection; GC/NPD) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade

agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Codex MRL for residues of pyriproxyfen is established in/on tea commodities.

C. Revisions to Petitioned-For Tolerances

Although the petitioner requested a tolerance for 15.0 ppm, the Agency is establishing a tolerance at 15 ppm, consistent with the current practices regarding significant figures for tolerance setting.

V. Conclusion

Therefore, 40 CFR 180.510 is being amended to increase the currently established tolerance for residues of pyriproxyfen in/on tea from 0.02 ppm to 15 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 4, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.510, revise the entry for tea in the table in paragraph (a)(1) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * *	* * *
Tea	15
* * * *	* * *

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[FR Doc. 2016-03608 Filed: 2/19/2016 8:45 am; Publication Date: 2/22/2016]